SPEVIGO IV
Billing and Coding Guide

Spevigo® (spesolimab-sbzo) injection

Coding for SPEVIGO IV*

Code Type	Code	Description
ICD-10-CM[1]	L40.1	Generalized pustular psoriasis
CPT®[2]	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
HCPCS[3]	J1747	Injection, spesolimab-sbzo, 1 mg **Modifier:** Add **JA** to indicate IV administration[4]
Revenue Code[5]	0636 0260	Drugs requiring detailed coding IV therapy: General

These codes are not all-inclusive; appropriate codes can vary by patient, site of care, and payer. Correct coding is the responsibility of the provider submitting the claim for item or service.

Please check with the payer to verify codes and billing requirements. LEO Pharma does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

How Supplied

NDC Code	NDC Descriptor	Strength
00597-0035-10	**1** carton containing **2** single-dose 450-mg/7.5-mL vials	900 mg per IV infusion

*The information provided by LEO Pharma regarding potential billing codes for SPEVIGO is for informational purposes only. It is not intended to constitute advice or be regarded as a substitute for advice. Providers should not rely upon the information as a basis for making any decisions and LEO Pharma makes no representations or warranties about the completeness, accuracy, reliability, or suitability of the information.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedural Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous.

INDICATION

SPEVIGO is indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SPEVIGO is contraindicated in patients with severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO. Reported hypersensitivity reactions have included drug reaction with eosinophilia and systemic symptoms (DRESS) and anaphylaxis.

WARNINGS AND PRECAUTIONS

Infections: SPEVIGO may increase the risk of infections. In patients with a chronic infection or a history of recurrent infection, consider the potential risks and expected clinical benefits of treatment prior to prescribing SPEVIGO. Treatment with SPEVIGO is not recommended in patients with any clinically important active infection until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur during or after treatment with SPEVIGO. If a patient develops a clinically important active infection, discontinue SPEVIGO therapy until the infection resolves or is adequately treated.

Risk of Tuberculosis: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with SPEVIGO. Avoid use of SPEVIGO in patients with active TB infection. Consider initiating anti-TB therapy prior to initiating SPEVIGO in patients with latent TB or a history of TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SPEVIGO treatment.

Hypersensitivity and Infusion-Related Reactions:

- Serious hypersensitivity reactions, including anaphylaxis and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported during and following administration of SPEVIGO. These reactions can occur with the first dose or subsequent doses.
- SPEVIGO is contraindicated in patients with severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO. If a patient develops signs of anaphylaxis or other serious hypersensitivity, discontinue SPEVIGO immediately and initiate appropriate treatment.
- If a patient develops mild or moderate hypersensitivity during an intravenous infusion or other infusion-related reactions, stop SPEVIGO infusion and consider appropriate medical therapy (eg, systemic antihistamines and/or corticosteroids). Upon resolution of the reaction, the infusion may be restarted at a slower infusion rate with gradual increase to complete the infusion.

Vaccinations: Prior to initiating SPEVIGO for treatment of GPP, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients during and for at least 16 weeks after treatment with SPEVIGO. No specific studies have been conducted in SPEVIGO-treated patients who have recently received live viral or live bacterial vaccines

Please see additional Important Safety Information throughout and accompanying Prescribing Information and Medication Guide.

SPEVIGO is available through the following specialty distributors or Accredo® specialty pharmacy

Specialty Distributors	Phone	Fax	Email
ASD	800-746-6273	800-547-9413	service@asdhealthcare.com
Cardinal Specialty*	855-855-0708	614-553-6301	specialtyonline@cardinalhealth.com
Cardinal Specialty PR	787-625-4200	787-625-4398	cuserv@cardinalhealth.com
McKesson Plasma & Biologics	877-625-2566	888-752-7626	mpborders@mckesson.com
McKesson Specialty Distribution	855-477-9800	800-800-5673	mshcustomercare-mspl@mckesson.com
Specialty Pharmacy			
Accredo Specialty	877-807-0812	888-302-1028	

* Emergency Delivery service for expedited product shipping may be available.

Access and reimbursement support for your patients

Contact your LEO Pharma Field Reimbursement Manager (FRM) if you or your staff have questions about the fulfillment process.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

ADVERSE REACTIONS

Intravenous SPEVIGO for Treatment of GPP Flare (Study Effisayil-1): Most common adverse reactions reported in ≥5% of patients treated with SPEVIGO in the clinical trial were asthenia and fatigue, headache, nausea, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection (UTI).

Specific Adverse Reactions

- **Infections:** The most frequent adverse reactions that occurred in subjects treated with intravenous SPEVIGO were infections. During the 1-week placebo-controlled period in Study Effisayil-1, infections were reported in 14% of subjects treated with SPEVIGO compared with 6% of subjects treated with placebo. Serious infection (UTI) was reported in 1 subject (3%) in the SPEVIGO group and no subjects in the placebo group. Infections observed through Week 1 in Study Effisayil-1 in subjects treated with SPEVIGO were mild (29%) to moderate (71%).
- **Drug Reaction With Eosinophilia and Systemic Symptoms (DRESS):** Two cases of DRESS were reported in Study Effisayil-1 in subjects with GPP who were treated with intravenous SPEVIGO. RegiSCAR DRESS validation scoring (with the following categories: "no," "possible," "probable," or "definite" DRESS) was applied to the reported cases. Reported cases were assessed as "no DRESS" and "possible DRESS."

Subcutaneous SPEVIGO for Treatment of GPP When Not Experiencing a Flare (Study Effisayil-2): Regarding the exposure-adjusted incidence rates for subjects on randomized treatment prior to receiving rescue treatment for flare or completing trial without a flare, the rate per 100-patient years for injection site reaction (including erythema, pain, swelling, induration, urticaria, and warmth at the injection site) was 31.6 for the subcutaneous SPEVIGO cohort (600 mg loading dose followed by 300 mg every 4 weeks) vs 12.7 for the placebo cohort. The rate per 100-patient years for UTI was 18 for SPEVIGO vs 0 for placebo. The rate per 100-patient years for pruritus was 8.8 for SPEVIGO vs 0 for placebo. The rate per 100-patient years for arthralgia was 13.3 for SPEVIGO vs 6 for the placebo cohort. There were 3 subjects who discontinued subcutaneous SPEVIGO due to treatment-emergent adverse events of psoriasis compared to no subjects in the placebo cohort who discontinued placebo for any treatment-emergent adverse event.

Safety in Study Effisayil-2 After Flare: In Effisayil-2, subjects who experienced a GPP flare and received at least one dose of an open-label single intravenous 900 mg dose of SPEVIGO were treated with open-label subcutaneous SPEVIGO 300 mg. These subjects (n=19) received subcutaneous dosing at every 12 weeks, which could have been increased to every 4 weeks based on GPPPGA total score or pustulation subscore increased by ≥1 from any previous open-label maintenance visit. The reported safety profile of open-label subcutaneous SPEVIGO use after treatment of GPP flare with open-label intravenous SPEVIGO use was consistent with the safety profiles of use of SPEVIGO from Trial Effisayil-1
and randomized controlled data from Trial Effisayil-2

Clinical Development of Spesolimab-sbzo

- **Guillain-Barre Syndrome (GBS):** Among approximately 835 subjects exposed to spesolimab-sbzo during clinical development, GBS was reported in 3 subjects who received various doses of spesolimab-sbzo via various methods of administration in clinical trials for unapproved indications.

SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of SPEVIGO for the treatment of GPP have been established in pediatric patients 12 years of age and older and weighing at least 40 kg. Use of SPEVIGO for this indication is supported by data from a randomized, placebo-controlled study, which included 6 pediatric subjects 14 to 17 years of age with a history of GPP treated with subcutaneous SPEVIGO (Study Effisayil-2), and evidence from an adequate and well-controlled study of intravenous SPEVIGO in adults with GPP (Study Effisayil-1), with additional pharmacokinetic analyses showing similar drug exposure levels in adults and pediatric subjects 12 years of age and older and weighing 40 kg or more. The safety and effectiveness of SPEVIGO in pediatric patients younger than 12 years of age or in pediatric patients weighing less than 40 kg have not been established.

For additional resources and enrollment forms, scan the QR code or visit spevigohcp.com

Please see additional Important Safety Information throughout and accompanying Prescribing Information and Medication Guide.

References: **1.** National Center for Health Statistics – ICD-10-CM. Index to Diseases and Injuries. Accessed February 24, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2.** CPT 2026 Professional Edition. American Medical Association. 4th Edition, Revised 2025. Chicago, ILL. **3.** Codify by AAPC. Drugs, administered by injection HCPCS Code range J0013-J7175. Accessed February 24, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **4.** Noridian Healthcare Solutions. Modifiers. Accessed February 24, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers **5.** Revenue codes. Accessed February 24, 2026. Noridian Healthcare Solutions. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes

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